



DOCUMENT REVIEW

Quality Implementing Procedure ID: YMP-LBNL-QIP-6.1, Rev. 8, Mod. 0

Effective: 09/20/02

1. PURPOSE

This Quality Implementing Procedure (QIP) defines the responsibilities and describes the Lawrence Berkeley National Laboratory (LBNL) supplementary requirements for documenting activities that constitute the Technical, Engineering Assurance (EA), Bechtel SAIC Company, LLC (BSC) Quality Assurance (QA) Representative and LBNL Management Review of Yucca Mountain Site Characterization Project (YMP) LBNL documents. Such documents include, but are not limited to Technical Products (e.g., Scientific Analysis/Model Reports, Process Model Reports [PMRs], Technical Report deliverables), scientific/engineering journal articles, internal LBNL reports, scientific notebooks, data, computer software qualification documentation, assigned portions of Technical Work Plans (TWP), Scientific Investigation Test Plans (SITP), YMP-LBNL-QIPs, and YMP-LBNL-Technical Implementing Procedures (TIPs).

This procedure is in full compliance with Office of Civilian Radioactive Waste Management (OCRWM) Administrative Procedures (AP)-2.14Q, *Review of Technical Products and Data*, AP-6.28Q, *Document Review* and applicable governing procedures. All external reviews of LBNL documents shall be conducted in accordance with AP-2.14Q or as directed by the governing procedure.

2. SCOPE

This QIP applies to the activities of the document Originator(s), the independent Technical Reviewer, the EA Reviewer, the BSC QA Representative, the Principal Investigator (PI), the Deputy Project Manager, and the Project Manager (PM) during the review process of any scientific document subject to the U. S. Department of Energy (DOE) OCRWM *Quality Assurance Requirements and Description* (QARD), DOE/RW-0333P. It also applies to the review of any YMP-LBNL QA procedures such as QIPs, or TIPs, technical reviews of scientific notebooks, data, software documentation and other project documents if determined to be necessary by the PM or designee.

Scientific Analysis Reports, Model Reports, PMRs, and other Technical Product deliverables also require a Check, a BSC Quality Engineering Representative (QER) Review and other reviews by affected organizations which are referenced but not specifically described in this procedure. Scientific Analysis Reports, Model Reports, PMRs, and other Technical Products are checked and reviewed in accordance with AP-SIII.9Q, *Scientific Analyses*, AP-SIII.10Q, *Models*, AP-3.11Q, *Technical Reports*, or other governing procedure. The TWPs are reviewed in accordance with AP-2.27Q, *Planning for Science Activities*. The SITPs are reviewed in accordance with AP-SIII.7Q, *Scientific Investigation Laboratory and Field Testing*. Software documentation is reviewed in accordance with AP-SI.1Q, *Software Management*. The required reviews for scientific notebooks are discussed in AP-SIII.1Q, *Scientific Notebooks*. The data reviews are conducted in accordance with AP-2.14Q.

3. PROCEDURE

3.1 Scientific Document Technical Review Requirements

The following technical, EA and Management review requirements are in effect for YMP-LBNL scientific documents:

3.1.1 Scientific Analysis Reports/Model Reports/PMRs/Technical Product Deliverables:

All required reviews associated with Scientific Analysis Reports shall be conducted in accordance with AP-SIII.9Q; Model Reports shall be reviewed in accordance with AP-SIII.10Q; and PMRs, and other Technical Products shall be reviewed in accordance with AP-3.11Q, or other governing procedure. Additionally, a minimum of one YMP-LBNL Technical Reviewer and one EA Reviewer will be assigned to review all YMP-LBNL Technical Product deliverables. All Technical Product deliverables shall be finally approved as required by the governing procedure or Management directives.

This process is intended to produce documents that are technically sound and that will meet the administrative and other requirements for supporting documents to the YMP license application process. Proper revision control shall be maintained on all drafts of the document as they move through Technical Review, EA review and all other required reviews (i.e., the Checker, QER review etc,) as described in Section 3.2.6. The Review Record and Comment Sheet (Attachments 2 and 4, respectively of this procedure) shall be used to document the YMP-LBNL technical and EA reviews.

This procedure provides for an additional evaluation process for Scientific Analysis Reports, Model Reports, PMRs, and Technical Products identified as a deliverable to the BSC or the OCRWM to assure the technical adequacy of the document, and the traceability and accuracy of source information as follows:

- A. "Technical Review": A technical content review shall be conducted by an independent YMP-LBNL Technical Reviewer from the same technical functional area as the Originator. The Deputy PM may direct that the Technical Review be completed before Checking, or that they be performed concurrently. The Technical Reviewer is assigned by the Deputy PM or designee to provide an overall assessment of the technical quality of the document, including the document's technical adequacy, correctness, completeness, accuracy, applicability to the issues being addressed, and compliance with technical review criteria identified in the applicable QA governing procedure for these documents (e.g., AP-2.14Q, AP-SIII.9Q, AP-SIII.10Q, AP-3.11Q, etc.). Additional technical review criteria may be identified on the Review Record, as deemed appropriate by the Deputy PM or designee.
- B. "EA Review": Prior to finalizing the document, an EA review shall be conducted by an independent EA Reviewer who is knowledgeable of the overall procedural requirements. The EA Reviewer is assigned by the Deputy PM or designee to ensure that the quality requirements (e.g., compliance with procedural requirements, management directives, etc.) are adhered to. Additional EA review criteria may be identified on the Review Record, as deemed appropriate by the Deputy PM or designee.

C. "Management Approval": The PM or designee shall review the document and associated review documentation to ensure the adequacy and completeness of the responses, and final resolution of comments. Approval shall be documented on the Review Record (Attachment 2) as described in Section 3.4.5.

3.1.2 Scientific Notebooks: Pertinent sections of scientific notebooks that support an Scientific Analysis Reports, Model Report, PMR, or other Technical Product deliverables shall be technically reviewed by a Checker or Technical Reviewer assigned to review the document. In addition, as a minimum annually or at notebook closeout, a Technical Review of scientific notebooks shall be performed for those elements that have not been previously reviewed. The reviewer shall be independent of the work produced and s/he shall not be the investigator's direct supervisor when the notebook is reviewed for closeout or submittal of data to the TDMS. The Review Record, Applicable Reference Information, and Comment Sheet (Attachments 2, 3, and 4, respectively of this procedure) shall be used to document the review of notebooks if no data submittal is involved. For notebook reviews that support data submittals, the AP-2.14Q required forms shall be used to document the review. The reviewers shall use the scientific notebook review criteria identified in AP-SIII.1Q.

Additionally, Compliance Reviews of scientific notebooks shall be performed of the initial entry and any amended initial entry (as part of the annual review). Compliance Reviews of scientific notebook contents shall be conducted annually and at notebook closeout in accordance with AP-SIII.1Q.

3.1.3 Data submitted to the TDMS: Data and pertinent section(s) of identified source documents (e.g., scientific notebook) shall be reviewed by a Technical Reviewer assigned to review the data prior to submittal of final technical data to the TDMS. The data reviewer shall be independent of the data originator and not the originator's direct supervisor. Data reviewers shall use the data review criteria identified in AP-2.14Q. The associated scientific notebook review will be conducted in accordance with AP-SIII.1Q. The associated software used for the data analysis shall be documented in accordance with AP-SI.1Q. The Key Technical Data Traceability form (Attachment 5) will be used to identify the data supporting documentation, (e.g., applicable scientific notebook pages, computer codes, etc.). The AP-2.14Q required review forms shall be used to document the review. The review documentation of data and associated source documents shall be transmitted to the Technical Data Coordinator. The Technical Data Coordinator is responsible for submitting the data to the TDMS in accordance with the AP-SIII.3Q, *Submittal and Incorporation of Data to the Technical Data Management System*. Documentation of transmittal of data to the TDMS, or the documentation accession number, shall be included in the corresponding scientific notebook.

3.1.4 Software Qualification Documentation: Each element or life cycle phase of software qualification documentation (e.g., Level 3: Software Management Report [SMR]; Level 2: Software Definition Report [SDR] and Software Implementation Report [SIR]; Level 1: Requirements Document [RD], Design Document [DD], Installation Test Plan [ITP], Validation Test Plan [VTP], Users Manual [UM] and Validation Test Report [VTR]) shall be reviewed by an independent Technical Reviewer in accordance with AP-SI.1Q.

An EA review shall be performed prior to approval by the Responsible Manager (RM) or RM Supervisor, as applicable.

The Technical Reviewer selected to perform the review shall be independent of all prior development and testing activities for the software. If the RM (i.e., PI) is the only individual who can perform the independent technical review, the RM Supervisor shall document the assignment of the RM (i.e., PI) as a reviewer with an explanation of the lack of independence in a memorandum to the RM (i.e., PI) and attach the memorandum to the applicable documents.

Technical and EA reviews shall be conducted and documented on the Review Copy in accordance with AP-SI.1Q using the software technical and procedural criteria documented in AP-SI.1Q. The purpose of the reviews shall be to verify that the products of, and/or results generated by, the phase meet the conditions or requirements imposed at the start of the phase (e.g., the products and results of the previous phase.) The LBNL Software Coordinator (SC) or designee shall be the Review Coordinator for required software reviews.

Upon completion of YMP-LBNL required reviews, level 1 codes documentation shall be submitted to the BSC Information Technology Software Management Analyst (ITSMA) Reviewer prior to Control Point 1 and Control Point 2 as well, as described in AP-SI.1Q.

3.1.5 Scientific/Engineering Journals and LBNL Reports: Submittals to scientific/engineering journals and LBNL reports shall be reviewed by a Technical Reviewer and a Technical Editor. An EA review is not required. Additional Earth Science Division review requirements may apply for the LBNL reports.

The Review Record and Comment Sheet (Attachments 2 and 4, respectively) or a marked-up copy of the document may be used to document the Technical Review. Technical Reviewer shall consider, at a minimum, whether the document is correct, technically adequate, complete, accurate. All YMP-LBNL publications shall be approved in accordance with AP-IST-004, *Public Release Review, Approval, and Distribution of Technical and Non-Technical Products*.

3.1.6 YMP-LBNL-QIPs, TIPs, assigned portions of TWPs, and SITPs:

A. Portions of TWPs assigned to YMP-LBNL shall be developed, reviewed and approved in accordance with AP-2.27Q. Additionally, a YMP-LBNL Technical and an EA Review shall be performed prior to final approval. The Review Record and Comment Sheet (Attachments 2 and 4, respectively) of this procedure shall be used to document these reviews. Technical Reviewers shall consider, at a minimum, whether the document is correct, technically adequate, complete, accurate, and in compliance with AP-2.27Q. Compliance with requirements described in AP-2.27Q shall be used as a basis for the EA review.

B. SITPs assigned to YMP-LBNL shall be developed, reviewed and approved in accordance with AP-SIII.7Q. Additionally, a YMP-LBNL Technical and an EA Review shall be performed prior to final approval. The Review Record and Comment Sheet (Attachments 2 and 4, respectively) of this procedure shall be used to document

the review. Technical Reviewers shall consider, at a minimum, whether the document is correct, technically adequate, complete, accurate, and in compliance with AP-SIII.7Q. Compliance with requirements described in AP-SIII.7Q shall be used as a basis for the EA review.

- C. QIPs shall be reviewed by two Technical Reviewers, an EA and BSC QA Representative Reviewer, and be finally approved by the PM or designee in accordance with YMP-LBNL-QIP-5.2, Preparing Quality and Technical Implementing Procedures. The EA and BSC QA Reviewers shall ensure that QA program requirements are adhered to. Compliance with requirements, as described in the applicable QA procedures, shall be used as a basis for the review criteria. The BSC QA Representative also reviews QIPs and the respective QARD Requirements matrix for compliance with QARD requirements.
- D. TIPs shall be reviewed by two Technical Reviewers, an EA and BSC QA Representative Reviewer, and be finally approved by the PI (if the PI is not the Originator) and PM or designee in accordance with YMP-LBNL-QIP-5.2. The EA and BSC QA Reviewers shall use the same criteria identified for QIPs above, as appropriate.

The same review requirements shall be in effect for any revisions as required by the applicable governing procedures. Revisions and modifications to YMP-LBNL QIPs and TIPs shall follow the requirements of YMP-LBNL-QIP-5.2.

3.2 Initiation of the Review Process

Required YMP-LBNL reviews as described in Section 3.1 (with the exception of 3.1.3 and 3.1.4) shall be performed as described below. The Deputy PM may direct that the Technical Review be completed before Checking, or that they be performed concurrently.

The following requirement steps apply to all Reviews, including the technical, the EA, and BSC QA reviews (for the QIPs/TIPs only.) As such, Technical Reviewer, EA Reviewer or BSC QA Representative Reviewer (for QIPs/TIPs only) may be substituted where Reviewer is identified below, as appropriate.

- 3.2.1 The document **Originator** (i.e., first or lead author, referred to as Originator throughout this QIP) shall have overall responsibility for the content of the document and shall notify the Deputy PM when a document is complete and ready for review.
- 3.2.2 The **Originator** shall schedule the review giving enough lead time to allow adequate review and documentation of the process. The Originator shall be the Review Coordinator unless designated otherwise by the Deputy PM. The Originator of a document begins the review process by requesting the Deputy PM or designee to appoint the Reviewer(s). The Originator may recommend a potential reviewer(s) to the Deputy PM or designee.
- 3.2.3 The **Deputy PM** or designee shall appoint a Technical Reviewer(s) who is technically competent in the subject area being reviewed and who did not directly participate in the authorship of the document or portion of the document (e.g., chapter) under review. To

be qualified as an independent Technical Reviewer, an individual shall be technically qualified (a peer of the Originator) in the scientific document subject area(s), or be similarly qualified in a user group subject area. The **Deputy PM** or designee shall:

- A. Select a sufficient number of Technical Reviewers to ensure that all areas of expertise addressed in the document are adequately reviewed.
- B. Document the selection of the Technical Reviewer(s) responsible for reviewing the document on the Review Record, as described in Attachment 2.

3.2.4 Documentation of Technical Reviewer, and EA Reviewer qualifications shall include a signed and dated Reviewer Qualification Verification Statement (RQVS) (Attachment 1), that shall be maintained by the **EA Manager** or designee prior to performance of the review. This need only be done once for each Technical or EA Reviewer, not for each review, as long as qualifications are relevant for the assigned documents. All reviewers shall follow the latest revision of this procedure, and the latest revision of the applicable governing procedure, to perform the review.

3.2.5 Each designated technical discipline, as identified by the Deputy PM in Section 3.2.3 A., shall review the document according to the established review criteria. Revisions to a document shall also be reviewed by the same technical disciplines.

3.2.6 The document **Originator** (or Review Coordinator) shall initiate the Review Record by following the instructions given for Attachment 2. Alpha numeric revision designators (e.g., Draft 00A, Draft 00B, etc.) shall be used to denote drafts reviewed in the development of the initial issue, prior to approval of the document by the required internal and external reviewers.

The Originator shall provide the reviewer with:

- a copy of the document to be reviewed (hereafter referred to as the Review Copy)
- the Review Record (Attachment 2)
- associated review criteria
 - criteria appropriate to the Technical Product being reviewed shall be identified
 - specific or additional review criteria determined to be appropriate (e.g., the governing procedure, TWP, SITP, QIPs)

Criteria shall be established prior to the review and shall include consideration of the applicability, correctness, technical adequacy, completeness, accuracy, and compliance with established requirements of the document under review. The technical review criteria described above may be supplemented as deemed appropriate.

- Comment Sheet (Attachment 4) and any additional pertinent background information (e.g., TWP).

- Applicable Reference Information (Attachment 3) listing the associated scientific notebooks and other source documents, if applicable. These documents shall be included in the scope of the review.
- Key Technical Data Traceability form (Attachment 5) identifying the applicable support documentation for data. The review forms required by AP-2.14Q, data review criteria identified in AP-2.14Q shall be used for data reviews.

3.3 Performance of Review

3.3.1 The **Reviewer(s)** shall consider all aspects of the document under review and evaluate the document(s) according to the review criteria identified on the Review Record (Attachment 2).

- A. The **Reviewer** shall clearly and legibly write all technical comments on the Comment Sheet (Attachment 4) and/or indicate that comments and other review documentation are on attached sheets. If comments are provided on an attachment, the comments shall be numbered both on the attachment and on the Comment Sheets. Mandatory comments shall be clearly labeled with an asterisk “*”; all other comments shall be considered non-mandatory. Editorial comments, such as spelling, grammar, or syntax may be made on the Review Copy itself.
- B. Mandatory comments are those comments that identify a problem such as a conflict with existing OCRWM requirements, failure to meet stated review criteria, or an inadequacy or error that could adversely impact the suitability of the document for its intended use. Mandatory comments require resolution.
- C. Non-mandatory comments are only suggested changes that shall be considered. However all technical comments whether mandatory or non-mandatory shall be responded to. If there are no technical comments, the Reviewer shall mark the Comment Sheet (Attachment 4) as such.
- D. When the review is complete, the **Reviewer** shall sign and date the Review Record (Attachment 2) and return it along with the Comment Sheet(s) (Attachment 4), the Review Copy, and any supplementary background documents to the Originator.

During resolution of comments and development of the revised Concurrence Draft, close communication between the Originator and the Reviewer(s) is encouraged. It may also be advisable for the Reviewers to communicate among themselves if more than one Reviewer is assigned to a document, particularly if conflicting comments have developed.

3.4 Response to Reviewer Comments

3.4.1 The document **Originator** shall consider and respond to all mandatory and non-mandatory technical comments. Originator responses shall document the response in the “Response” column of the Comment Sheet (Attachment 4). The originator need not accept each mandatory comment, but the rejection of specific mandatory comments and the reasons for rejection shall be recorded on the Comment Sheet. Editorial comments

need no response. The Originator shall revise the draft document as discussed in the "Response" and sign the Review Record. The resulting revised Concurrence Draft of the document, Review Copy, Review Record, and Comment Sheet(s) shall be returned to the reviewer(s) for mandatory and non-mandatory technical comment resolution and concurrence.

3.4.2 The Reviewer(s) shall:

- A. Review the responses on the Comment Sheet and the revised Concurrence Draft, and compare it to the Review copy and any associated documentation; evaluate the responses to mandatory and non-mandatory technical comments for acceptability and review the revised document/data set to ensure that the Concurrence Draft meets the review criteria, including any new criteria or review instructions that may have resulted from the initial review.
- B. Indicate acceptance of the Originator's response by initialing and dating the "Accept" column of the Comment Sheet, or reject by leaving the "Accept" column blank. If responses to all mandatory technical comments are accepted, the Reviewer shall indicate this by signing the "Concurrence" section of the Review Record (Attachment 2).

3.4.3 Direct interaction between the **Originator** and **Reviewer(s)** is encouraged to resolve outstanding issues. If the reviews are performed concurrently and conflicting comments are generated, it is the responsibility of the Originator or designated Review Coordinator to assure the comments are resolved satisfactorily with the reviewers. When such issues cannot be resolved, they shall be referred to the PM or designee for resolution. Unresolved issues involving YMP-LBNL staff and the BSC QA Representative shall be referred to successively higher levels of management within YMP-LBNL and BSC QA management for resolution.

3.4.4 The **Originator** and **Reviewer(s)** shall resolve unacceptable responses and document the resolution thereof on an additional Comment Sheet (if needed) or memorandum to be included in the review package, or elevate disputed issues to appropriate management, if necessary.

3.4.5 The **PM** or designee (and BSC QA management for BSC QA reviews) shall discuss each unresolved mandatory technical comment with the parties involved and make the final determination of their resolution. The resolution shall be documented on the Comment Sheet or an attached memorandum and be cross-referenced on the Comment Sheet. Once all issues are resolved, the PM (and BSC QA management, as applicable) shall indicate the satisfactory final resolution of all items by signing and dating the "Accept" column of the Comment Sheet and the "Dispute Resolution" section of the Review Record.

3.4.6 The **Deputy PM** or designee shall review the Review Record, Comment Sheet(s), Review Copy Mark-up, and revised Concurrence Draft document to ensure the review process is appropriately documented and there is record of response and resolution of all mandatory technical comments. The Deputy PM or designee shall indicate his/her approval by signature on the "Concurrence" section of the Review Record.

3.5 Approvals

The **Originator** shall then:

3.5.1 Produce the final document by changing the alphanumeric designator to a numeric designator (the initial analysis designator is 00 and subsequent revisions are 01, 02, etc.).

3.5.2 Obtain approval signatures as follows:

- Technical Products, TWPs SITPs- in accordance with requirements of the governing procedure or management directive
- QIPs and TIPs – Originator, Technical Reviewers, EA Reviewer, BSC QA Representative Reviewer, and PM on the procedure approval sheet

3.5.3 For release to the public, submit the document for review, approval and distribution in accordance with AP-IST-004, *Public Release Review, Approval, and Distribution of Technical and Non-Technical Products*.

3.6 Data and Records Submittal

The **Originator** shall transfer reviewed data to the Technical Data Coordinator for submittal to the TDMS in accordance with the AP-SIII.3Q. A Key Technical Data Traceability form (Attachment 5) which identifies the data supporting documentation and the review forms required by AP-2.14Q shall accompany the data submittal. The **Technical Data Coordinator** shall ensure that all the applicable records identified in Section 4.1 below, and in the applicable governing procedure, are submitted to the Records Coordinator for RPC submittal.

Approved YMP-LBNL controlled documents shall be submitted to the Records Coordinator for distribution according to AP-6.1, *Controlled Documents*. Completed documents shall have a records package with all appropriate documentation prepared and submitted to the YMP RPC according to AP-17.1Q, *Record Source Responsibilities for Inclusionary Records*.

4. RECORDS

4.1 QA Records

- Final reviewed documents/data
- Reviewer Qualification Verification Statement
- Review Record/Comment Sheet(s)
- Applicable Reference Information, if scientific notebooks reviewed
- Key Technical Data Traceability, if data reviewed

4.2 Non-QA Inclusionary Records

Review Drafts.

4.3 Non-QA Exclusionary Records

None.

5. RESPONSIBILITIES

- 5.1** The **Project Manager (PM)** or designee is responsible for the approval of the QIPs and TIPs and the final disposition of disputed comments.
- 5.2** The Deputy Project Manager or designee is responsible for appointing Checkers/Technical/EA Reviewers for YMP-LBNL documents on the basis of education, training and experience. The Deputy PM or designee is also responsible in assigning specific review criteria as deemed appropriate. The Deputy PM or designee shall review the documentation associated with the technical, EA and BSC QA review process to assure that it has been properly completed and indicate approval on the Review Record once associated documentation has been reviewed for completeness.
- 5.3** The **Engineering Assurance (EA) Manager** or designee is responsible for providing assistance/guidance to staff members in the review process. The EA Manager or designee is also responsible for ensuring that all Technical and EA Reviewers, who do not have previously documented qualifications on file, fill out the RQVS form prior to performing the review.
- 5.4** The document **Originator** (first or lead author, referred to as Originator throughout this QIP) is responsible for scheduling and coordinating the review process. If the first author is not available, another author may be designated by the Deputy PM to do so. The Originator shall identify the review scope and criteria on the Review Record, distribute copies of the review forms and the document being reviewed to the designated Technical and EA Reviewers along with applicable pages of scientific notebooks, background information, and data to be reviewed. Upon return of reviews, the Originator shall respond to all mandatory and non-mandatory technical comments made by the reviewers. The SC shall perform the review coordination for the software reviews.
- 5.5** The **Review Coordinator** (if designated by the Deputy PM to be someone other than the Originator) is responsible for scheduling and coordinating the review process as described for the Originator above. The Review Coordinator is also responsible for ensuring that all Technical and EA Reviewers have documented qualifications on file, including the RQVS form prior to performing the review.
- 5.6** **Technical Reviewer(s)** is responsible for reviewing the document, providing written comments on the Comment Sheet or attached documentation, and evaluating/accepting Originator responses. Comments shall be returned to the Originator in a timely manner.
- 5.7** The **BSC QA Representative** is responsible for reviewing the QIPs, the TIPs, and the QARD Requirements matrix for compliance with applicable QARD requirements.

6. ACRONYMS AND DEFINITIONS

6.1 Acronyms

BSC	Bechtel SAIC Company, LLC
CRWMS	Civilian Radioactive Waste Management System
DD	Design Document
DOE	U.S. Department of Energy
EA	Engineering Assurance
ITP	Installation Test Plan
ITSMA	Information Technology Software Management Analyst
LBNL	Lawrence Berkeley National Laboratory
PI	Principal Investigator
PM	Program Manager
PMR	Process Model Report
RM	Responsible Manager
QA	Quality Assurance
QER	BSC Quality Engineering Representative
QARD	Quality Assurance and Requirements Document
OCRWM	Office of Civilian Radioactive Waste Management
QIP	Quality Implementing Procedure
RD	Requirements Document
RPC	Records Processing Center
RQVS	Reviewer Qualification Verification Statement
SC	Software Coordinator
SDR	Software Definition Report
SIR	Software Implementation Report
SITP	Scientific Investigation Test Plans
SMR	Software Management Report
TDMS	Technical Data Management System
TWP	Technical Work Plan
TIP	Technical Implementing Procedure
UM	Users Manual
VTP	Validation Test Plan
VTR	Validation Test Report
YMP	Yucca Mountain Site Characterization Project

6.2 Definitions

Concurrence Draft: A draft of a scientific document or data set that has been revised to incorporate comments generated by Reviewer(s), and that is considered by the document/data Originator to be ready for concurrence and approval.

Data Originator: Individual responsible for collecting, developing, and assembling scientific data.

Editorial Comments: Comments made to a document such as correcting grammar, spelling, or obvious typographical errors; renumbering sections or attachments (as long as the renumbering

does not affect the chronological sequence of work); modifying the title or number of the document (as long as the fundamental process is not changed); updating organizational titles (as long as responsibilities are not changed); or making other corrections or clarifications of intent that do not alter the results or the way a document is used.

Governing Procedure: The document invoking implementation of a procedure.

Management Approval: The Deputy PM or designee review of the document and the completeness of the review processes to ensure resolution of all mandatory comments. The Deputy PM or designee concurrence is provided on the Review Record.

Mandatory Comments: A comment requiring resolution that identifies a problem such as a conflict with existing OCRWM requirements, failure to meet stated review criteria, or an inadequacy or error that could adversely impact the suitability of the document for its intended purpose.

Model: A model representation of a system, process, or phenomenon, along with any hypotheses required to describe the process or system or explain the phenomenon, often mathematically (QARD).

Non-mandatory comments: Technical comments that are suggested changes. All technical comments designated as non-mandatory require a response.

Originator: The first or lead author who has overall responsibility for preparing a scientific document and overseeing persons who have made material contributions to the work and composition, and who accepts professional responsibility for its contents.

Review Draft: A complete (e.g., Technical Review) draft of a scientific document or data set including all text, figures, tables and any supporting appendices, that is considered by the document/data Originator to be ready for review.

Scientific Analysis: A documented study that 1) defines, calculates, or investigates scientific phenomena or parameters; 2) evaluates performance of components of aspects of the overall geologic repository; or 3) solves a mathematical problem by formula, algorithm or other numerical method.

Technical Product deliverable: Any item containing engineering or scientific information with relevance to the characterization, design, and/or operation of the Civilian Radioactive Waste Management System (CRWMS). Examples include:

- Scientific Analyses Reports
- Calculations
- Models Reports
- Process Model Reports, etc.

Technical Reviewer: A technically competent individual, other than the Originator, from the same technical area as the Originator, assigned by the Deputy PM with education, training and experience that allows him/her to understand/evaluate the contents of the document being

reviewed. A reviewer shall not have participated in the authorship of the portion of the document (e.g., chapter) under his/her review.

7. REFERENCES

- DOE/RW-0333P, Quality Assurance Requirements and Description
- AP-2.14Q, Review of Technical Products and Data
- AP-2.27Q, Planning for Science Activities
- AP-3.11Q, Technical Reports
- AP-6.1Q, Controlled Documents
- AP-6.28Q, Document Review
- AP-17.1Q, Record Source Responsibilities for Inclusionary Records
- AP-SI.1Q, Software Management
- AP-SIII.1Q, Scientific Notebooks
- AP-SIII.3Q, Submittal and Incorporation of Data to the Technical Data Management System
- AP-SIII.7Q, Scientific Investigation Laboratory and Field Testing
- AP-SIII.9Q, Scientific Analyses
- AP-SIII.10Q, Models
- AP-IST-004, Public Release, Review, Approval, and Distribution of Technical and Non-Technical Products
- YMP-LBNL-QIP-5.2, Preparing Quality and Technical Implementing Procedure

8. ATTACHMENTS

Attachment 1: Reviewer Qualification Verification Statement

Attachment 2: Review Record

Attachment 3: Applicable Reference Information

Attachment 4: Comment Sheet

Attachment 5: Key Technical Data Traceability

9. REVISION HISTORY

09/06/95 – Revision 0, Modification 1:

Modification to address administrative and grammatical changes.

12/07/95 – Revision 0, Modification 2:

Modification to incorporate review criteria directly into procedure based on comments raised during audit.

Modification to require two technical reviews for documents and to address that technical documents unless specified in an applicable procedure, do not require a QA review.

09/09/96 – Revision 1, Modification 0:

Revised procedure to reflect requirement changes in QARD, Rev. 5.

06/02/97 – Revision 2, Modification 0:

Revised procedure to introduce the term Engineering Assurance (EA) and to identify the role and responsibilities of the EA Manager and OQA representative in document reviews.

06/05/98 – Revision 3, Modification 0:

Revised procedure to incorporate provision for inclusion of pertinent sections of scientific notebooks supporting milestone deliverables in the review criteria. Included provision for management review of completeness of the DRCR documentation. All document pages are affected. All DRCR documentation is undergoing management review for completeness; procedural changes in this revision have no impact on previous project activities.

01/08/99 – Revision 4, Modification 0:

Revised entire procedure to make consistent with M&O interim guidance documents and to include provision for the Check Review and Technical Review of documents/data/scientific notebooks. Additionally revised review criteria and added review criteria for the Check Review, and the scientific notebook Check Review and Technical Review.

10/29/99 – Revision 5, Modification 0:

Revised entire procedure to make consistent with recently issued OCRWM APs/QAPs as applicable, included cross-reference to procedures containing Checker requirements, revised general review criteria, and retained LBNL requirements for reviews which are consistent with applicable upper-tier APs.

09/22/00 – Revision 6, Modification 0:

Ensured consistency with AP-2.14Q and AP-6.28Q. Revised to change the Development Plan activities to follow the Technical Work Plan activities of AP-2.21Q. Updated review criteria in Attachment 5 to be consistent with upper-tier documents, as applicable.

03/02/01 - Revision 7, Modification 0:

Made text and Review Form consistent with AP-2.14Q. Included data criteria from AP-2.14Q to be used. Changed title from OQA on-site representative to M&O QA Representative to reflect organizational changes initiated by the new M&O.

03/15/02 – Revision 7, Modification 1:

Modification to replace the M&O with the BSC. Made changes to text for consistency with AP-2.21Q, AP-2.14Q, AP-SI.1Q, AP-SIII.1Q, AP-SIII.7Q, AP-SIII.9Q, and AP-SIII.10Q. Included the Deputy PM responsibilities. Updated review criteria.

09/20/02 – Revision 8, Modification 0:

Modification to remove reference to the review criteria identified in the previous version of this procedure, as discussed in Deficiency Report LBNL(B)-02-D-155. Removed reference to the cancelled AP-2.21Q and replaced with AP-2.27Q. Streamlined the requirements listed herein with AP-2.27Q and AP-SIII.7Q. Removed reference to the check and QER reviews and referenced the applicable governing procedures.

10. APPROVALS

(signature on file)
Preparer: Vivi Fissekidou

Date:

(signature on file)
Technical Reviewer: Ardyth Simmons

Date:

(signature on file)
Technical Reviewer: Yvonne Tsang

Date:

(signature on file)
EA Reviewer: Nancy Aden-Gleason

Date:

(signature on file)
BSC QA Concurrence: Stephen Harris

Date:

(signature on file)
Project Manager: Gudmundur Bodvarsson

Date:

YMP-LBNL

Reviewer Qualification Verification Statement

(To be signed prior to reviewing)

☐ Technical Reviewer ☐ EA Reviewer

Name: _____ Date: _____

Organization: _____

Technical Expertise: _____

Basis of Qualification (Brief Résumé):

I certify that the above or attached information is correct.

Technical/EA Reviewer signature

Date

The above Technical/EA Reviewer meets the education and experience requirements to perform reviews in the specified area of technical expertise.

Project Manager signature

Date

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YMP-LBNL-QIP-6.1, Rev. 8, Mod. 0
Attachment 2
Page 1 of 3

YMP-LBNL REVIEW RECORD						1. QA: QA 2. Page of
3. Responsible Manager: Project Manager (PM): Gudmundur S. Bodvarsson		3a. Originator/Comment Responder:				
4. Document * Title: _____						
5. Document * Identifier: _____		6. Revision/Mod./Review Draft: _____		7. Date: _____		
8. Governing Procedure Number: _____		9. Governing Procedure Revision/Mod: _____				
REVIEW CRITERIA <div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> 10. <input type="checkbox"/> Standard Review Criteria _____ 12. Comment Documentation: <input type="checkbox"/> Comment Sheets <input type="checkbox"/> Review Copy Mark-up </div> <div style="width: 48%;"> 11. <input type="checkbox"/> Specific Review Criteria (QIP, QARD, AP, etc.): <input type="checkbox"/> Source: _____ <input type="checkbox"/> Attached: _____ <input type="checkbox"/> Scientific notebook pages associated with technical notebook review (see Attachment 3) </div> </div>						
13. Reviewer	Org./Discipline	Review Criteria	Reviewer	Org./Discipline	Review Criteria	
_____	_____	_____	_____	_____	_____	
_____	_____	_____	_____	_____	_____	
_____	_____	_____	_____	_____	_____	
COMMENTS DUE: 14. Due Date: _____ 15. Originator/Review Coordinator: _____ Print Name		REVIEW BY: 16. _____ Print Name 17. _____ Signature Date 18a. Mandatory Comments: <input type="checkbox"/> Yes <input type="checkbox"/> No 18b. Non-Mandatory Comments: <input type="checkbox"/> Yes <input type="checkbox"/> No ORIGINATOR/COMMENT RESPONDER (After response completed): 19. _____ Signature Date		CONCURRENCE: 20. Document Concurrence Draft No: _____ 21. Reviewer: _____ Signature Date 22. PM: _____ Signature Date DISPUTE RESOLUTION: (if applicable) 23. PM: _____ Signature Date		

*For data reviews use the AP-2.14Q required form along with YMP-LBNL-QIP-6.1, Key Data Traceability (Attachment 5)

INSTRUCTIONS FOR COMPLETING THE REVIEW RECORD**RESPONSIBLE MANAGER OR DESIGNEE:**

1. Identify the Quality Assurance (QA) designator (for a Q-designated Document or Data, enter "QA"; for a non-designated Document or Data, enter "N/A").
2. Identify the total number of pages for the Review Record (e.g., if 1 page of specific review criteria is included or Attachments 3 [Applicable Reference Information] or 6 [Key Technical Data Traceability] is attached, identify as page 1 of 2, 2 of 2).
3. Enter name of the Responsible Manager.
- 3a. Identify the Document Originator /Comment Responder.
4. Record the title of Document to be reviewed.
5. Record the Document Identifier or number of the Document to be reviewed (e.g., MDL-NBS-HS-000002).
6. Record the proposed revision/modification or ICN/review draft number, as applicable (e.g., Rev 1 Mod 0, Draft 00A).
7. Record the date of the Document to be reviewed, as applicable.
8. Identify the procedure invoking the review. Mark "N/A" if not applicable.
9. Identify the revision/modification or ICN, as applicable, of the procedure invoking the review.
10. Identify the standard review criteria that apply, check box and identify the source of the standard review criteria.
11. If specific review criteria apply, mark appropriate box. Identify where the review criteria can be located (e.g., YMP-LBNL-QIP-5.2, Rev 3, Mod 0). Check box if scientific notebooks are to be reviewed as part of this review (if so, append Attachment 3 and identify notebook ID #/pages to be reviewed). If data are being reviewed use the AP-2.14Q required forms and append Attachment 5 to identify supporting documentation.
12. Check box to identify comment documentation method (Comment Sheets shall be used for Technical/EA/BSC QA Reviewers) Review Copy Mark-up may be used for journal articles.
13. Identify the Reviewers, organization/discipline and the standard review criteria (or unique review criteria) assigned to each reviewer. Leave unused lines blank.
14. Assign a due date for the return of the comments.
15. Print name of Originator/Review Coordinator.

REVIEWER

16. Print name of Reviewer assigned.
17. Signature and date the review once the review has been completed.
- 18a. Check "Yes" or "No" to indicate whether mandatory comments are provided.

18b. Check “Yes” or “No” to indicate whether non-mandatory comments are provided.

ORIGINATOR/COMMENT RESPONDER:

19. Sign and date when responses to comments have been completed.

REVIEWER (if comments are accepted):

20. Record the review draft number (e.g., 00A, 00B), of the Concurrence Draft of the Document or Data.

21. Sign and date.

DEPUTY PROJECT MANAGER (if review documentation complete, give management review concurrence)

23. Sign and date.

CONCURRING MANAGER (complete if Reviewer does not concur with a technical mandatory response(s):

Upon resolution of disputed issue(s):

20. Record the review draft number (e.g., 00A, 00B), of the Concurrence Draft of the Document or Data.

21. Mark N/A

22. Sign and date.

23. Sign and date; and print organization of concurring Manager(s), as applicable.

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Attachment 3
Page 1 of 1

Document No.and Title: _____

Document(s) Title

Relevant Sections/Pages

[illegible]

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YMP-LBNL-QIP-6.1, Rev. 8, Mod. 0

Attachment 4

Page 1 of 1

YMP-LBNL COMMENT SHEET				
1. Document Title:			2. Page _____ of _____	
3. Document No.		4. Revision/ Change/Mod:	5. Draft	6. <input type="checkbox"/> QA <input type="checkbox"/> Non QA: N/A
7. Reviewer:				
8. NO. CODE	9. SECT./PARA./P# ¹	10. COMMENT	11. RESPONSE	12. ACCEPT ²

¹ Identify mandatory comments with an " * ".² Leave blank if you do not accept the response.

KEY TECHNICAL DATA TRACEABILITY

Date: _____ Data Tracking Number: _____

Prepared By: _____

Title/Subject: _____

The following contain supporting documentation for the attached data submittal. These documents have been, or shall be submitted to YMP Records Processing Center.

Notebooks/source

document: _____

ID#

Page Numbers

ID#

Page Numbers

ID#

Page Numbers

Photos: _____ ID (if possible) ID (if possible)

Maps: _____ ID (if possible) ID (if possible)

Computer
Files: _____ Filename Filename

Software codes/routines Used to generate the data:

Other: _____

Principal Investigator's Name Signature Date

Technical Data Coordinator's Name Signature Date